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Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _K131897_____

1. Date of Submission: Jun 19, 2013

2. Sponsor Identification

Vales & Hills Biomedical Tech. Ltd
Bldg 46-1 BDA International Business Park, 100176, Beijing, P.R. China

Establishment Registration Number: Not yet registered

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Position: Quality Manager
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: CV3000 Holter Analysis System
Proposed Device Common Name: Dynamic ECG System

Regulatory Information:
Classification Name: Electrocardiograph, Ambulatory, With Analysis Algorithm
Classification: II;
Product Code: MLO
Regulation Number: 21CFR 870.2800
Review Panel: Cardiovascular;

Intended Use Statement:
The proposed device is intended to continuously acquire ambulatory ECG data for up to twelve leads or five leads. It can record the ECG data for twenty four hours. The ECG data obtained will be stored in the recorder first and then download to PC for analysis, reviewing and printing by a trained physician in health facilities.

5. Predicate Device Identification

510(k) Number: K101273
Product Name: Dynamic ECG Systems, TLC5000
Manufacturer: CONTEC Medical System Co., Ltd

6. Device Description

The CV3000 Holter Analysis System is intended to continuously acquire ambulatory ECG data for up to twelve leads or five leads. It can record the ECG data for twenty four hours. The ECG data obtained will be stored in the recorder first and then download to PC for analysis, reviewing and printing by a trained physician in health facilities.

The CV3000 Holter Analysis System is consisting of Holter recorder and the PC-based CV3000 Analysis Software.

The Holter recorder is an ambulatory electrocardiograph designed to be used with the PC-based CV3000 Analysis Software. It is intended to acquire, record and store up to 24 hours of ECG data from the patient. It performs no cardiac analysis by itself and is intended to be used with the CV3000 analysis software. ECG data prerecorded by the Holter recorder is analyzed by the CV3000 analysis software.

The main accessories contain disposable electrodes, cables, SD card, SD card reader and battery. The disposable electrodes and battery is not provided during marketing, the users need purchase disposable electrode/battery by themselves.

The collateral devices contain personal computer (PC) and printer.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:1988+A1:1993+A2:1995, Medical electrical equipment, Part 1: General requirements for safety.

IEC 60601-1-2:2007, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and teats.

ANSI/AAMI EC38:2007, Ambulatory electrocardiographs

ANSI/AAMI EC 57:1998(R) 2003, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	Proposed Device CV3000 Holter Analysis System	Predicate Device K101273
Product Code	MLO	Same
Regulation Number	21 CFR 870.2800	Same
Operation mode	Automatic	Same
Time constant	≥3.2s	Same
Patient leak current	<10μA	Same
Frequency response	0.05～40 Hz	Similar
Noise level	<50μV	Similar
CMRR	>80dB	Similar
Scan speed	5 mm/mV,10 mm/mV, 20 mm/mV, error ±10%	Unknown
Measurement Function	Have measurement function	Have measurement function

The proposed device, CV3000 Holter Analysis System, is determined to be Substantially Equivalent (SE) to the predicate device, Dynamic ECG Systems, TLC5000 (K101273), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Vales & Hills Biomedical Tech. Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, CH 200120

Re: K131897
Trade/Device Name: Cv3000 Holter Analysis System
Regulation Number: 21 CFR 870.2800
Regulation Name: Dynamic Ecg System
Regulatory Class: Class II
Product Code: MLO
Dated: October 15, 2013
Received: October 24, 2013

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K131897
Device Name: CV3000 Holter Analysis System

Indications for Use:

The proposed device is intended to continuously acquire ambulatory ECG data for up to twelve leads or five leads. It can record the ECG data for twenty four hours. The ECG data obtained will be stored in the recorder first and then download to PC for analysis, reviewing and printing by a trained physician in health facilities.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

OR

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.11.26 15:51:01 -05'00'